

09/810,920 12969-1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)

Group Art Unit: 1714

BITLER, Steven P. et al.)

Examiner: Peter A. Szekely

Serial No.: 09/810,920)

Filing Date: March 16, 2001)

For: POLYMERIC)

THICKENERS FOR)

OIL-CONTAINING)

COMPOSITIONS

Pasadena, California

DECLARATION OF DAVID C. STEINBERG
UNDER 37 C.F.R. § 1.132Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

I, David C. Steinberg, declare that:

I. MY BACKGROUND

1. As detailed below, I am an expert in the chemistry of cosmetic products. Attached is my CV and list of publications. These documents truly and correctly represent my experience and publications.
2. I founded in 1995 and am currently the CEO of Steinberg & Associates, Inc., a consulting firm for the cosmetic industry specializing in the chemistry of cosmetic

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- ingredients, preservatives and preservation, international and U.S. cosmetic regulations, and marketing of raw materials to the personal care industry.
3. From 1982 to 1995, I worked for Sutton Laboratories (acquired by International Specialty Products ("ISP") in 1989) in several capacities including Vice President, Senior Industry Fellow and Worldwide Director of Technical Services and Applications for ISP. Senior Industry Fellows are the highest level of scientific personnel at ISP. When I was a Senior Fellow, there were only 3 out of approximately 15,000 employees. As Worldwide Director, five laboratories located throughout the world reported to me and I coordinated technical services and customer requirements.
 4. I have authored 3 books, 6 chapters of books, and 38 articles and I have co-authored 1 book and 2 chapters of books, as listed in the attached list of publications. All of the articles and half of the books relate to the chemistry of cosmetic ingredients. The remainder relate to cosmetic regulations. In addition, I have served on the editorial boards of the *Journal of Cosmetic Science* and the *Journal of Applied Cosmetology* and have been on the advisory board of *Cosmetics & Toiletries* magazine since 1997.
 5. My work in the chemistry of cosmetic ingredients has led to me being elected a Fellow of the Society of Cosmetic Chemists. The Society of Cosmetic Chemists has also honored me with their Merit Award. I was named Eminent Visiting Scholar by Virginia State University and, in 1988, I received the paper of the year award from the Australian Society of Cosmetic Chemists.
 6. From 1982 to 2000, I was an Adjunct Assistant Professor of Chemistry in the Graduate School of Chemistry at Fairleigh Dickinson University. I am also the inventor of the invention claimed in U.S. Patent No. 5,888,486 for antiperspirant composition.

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7. In 2000-1, I worked as a consultant for Dock Resins Corporation, which is owned by Landec Corporation, I was paid \$ 5,000 plus expenses by Dock Resins Corporation for this work. I am drafting this declaration as a consultant for Landec Corporation. I am being paid \$350/hour for my time drafting this declaration.

II. MATERIALS REVIEWED

8. I have read and I understand the written specification and the amended claims in U.S. patent application S/N 09/810,920, filed March 16, 2001 and I read and understood the rejection mailed by the U.S. Patent and Trademark Office on July 31, 2002 (paper no. 10) rejecting the specification on the grounds that it introduces new matter into the disclosure; rejecting claims 1, 5, 9-12, 20-25 and 37-40 on the grounds that they contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention and on the grounds that they contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains or with which it is most nearly connected, to make and/or use the invention; and rejecting claims 1, 5, 9-12, 20, 37 and 38 as anticipated by Mueller et al. 5,281,329; and rejecting claims 1-5, 9-12, 20, 32-38, 43 and 44 as being unpatentable over Mueller et al. 5,281,329.

III. MY OPINIONS AND FACTUAL BASIS FOR OPINIONS

- A. The inventors had possession of the claimed invention.

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9. It is my opinion that the language "The polymeric thickener should be used in an amount sufficient to thicken the oil" is inherently within the original disclosure and one skilled in the art would recognize that this was disclosed. Further, It is my opinion that the original disclosure reasonably conveyed to one skilled in the art that the inventor had possession of the claimed subject matter at the time of filing, in particular the subject matter of claims 1-5, 9-12, 20-25 and 37-40. Facts supporting this opinion are as follows. There are many places where this is clearly stated, including the following:
- i. Page 2 lines 8-10. Here the specification states that the SCC polymer crystallizes into a network in which the polymers are connected to one another. It is clear that you must have sufficient polymer present to accomplish this.
 - ii. Page 5 lines 27-8. This excerpt refers to examples 1-8 using 5 parts of polymer to thicken a light oil. The Table 1 on page 13 summarizes these examples and shows the clear increase in viscosity depending on the type of polymer. It is obvious that you need enough polymer present to affect the viscosity.
 - iii. Page 6 lines 15-8. Here the specification talks about using two polymers being able to be used together to obtain the thickening. This tells us that there is some minimum level where thickening does not occur because of insufficient polymer being added.
 - iv. Page 10 lines 14-9. Here the specification instructs that the amount of polymer needed is less than 10% but says it typically is 2 to 7%. It is clear that you must add sufficient amounts to thicken depending on the polymer and the oil.
 - v. Page 13, table 1. The table shows at a constant level of 5% you get different viscosities for different oils.

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10. From all of these statements it is clear to one of ordinary skill in the art that you must add sufficient polymer to achieve the desired thickness and that this increase in thickness occurs as you increase the amount of polymer until you cause the polymer to crystallize out and then you have no increase or possible decrease in viscosity.

B. The Inventors enabled the claimed invention.

11. It is my opinion that the claimed subject matter is described in the original specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected to make and/or use the invention without undue experimentation, in particular, the subject matter of claims 1-5, 9-12, 20-25, and 37 -40. Facts supporting this opinion are as follows.

- i. The specification as filed, on page 10, lines 14-18, teaches the amounts of the SCC polymer which are preferably used to thicken the oil. Tables 1 and 2 provide specific examples of thickened oils.
- ii. The thickening of oils by the addition of suitable additives is a well-known technology, as evidenced by the numerous prior art documents that are of record in this application. For example, U.S. Patent No. 5,736,125 (Morawsky), which is referred to in the application as filed (see page 1, lines 19-20) and which is now explicitly incorporated by reference, states in column 3, lines 19-21

In the compositions, the amount of thickening copolymer... is present in an amount sufficient to thicken the composition to the desired thickness.

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- iii. Those skilled in the art will have no difficulty, therefore, having regard to their own knowledge, the disclosure of this application, and routine experimentation, in determining the amounts of SCC polymer to be used for thickening oils. In fact, using the compounds (polymers) and oils disclosed in the specification, it would only take one skilled in the art and having the necessary equipment a short amount of time to determine the amount of polymer needed to achieve the desired thickness.

The undersigned, being hereby warned that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001, and that such willful false statements may jeopardize the validity of the Simon et al. application or any resulting patent, declares that all statements made of his own knowledge are true and that all statements made on information and belief are believed to be true.

Dated: 10/17/62By David C. Steinberg

David C. Steinberg

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*Curriculum Vitae***David C. Steinberg**

Education: BS Chemistry, Drexel University, 1965
MBA Management, Pace University, 1969

Occupation: 1995 Founded Steinberg & Associates, Inc.
A consulting firm for the Cosmetic industry
Specializing in the Chemistry of Cosmetic Ingredients,
Preservatives and preservation, International & US
Cosmetic Regulations, and marketing of raw materials

1982-1995 Sutton Laboratories (acquired by ISP in 1989)
1994- Worldwide Director, Technical Services and
Applications, Skin Care-ISP
1994 Named Senior Industry Fellow
1988-94 Vice President, Sutton Labs
1982-87 Sales Manager, Sutton Labs

1979-1982 Tri-K Industries
1981-82 Manager, Technical Services
1979-81 Technical Sales Representative

1978 Miranol Chemical, Technical Sales

1977 Scher Chemical, Vice President

1976 Chattem Drug and Chemical Company-Technical
Advisor

1969-76 Emery Industries
1974-6 Manager Cosmetic Specialties
1969-4 Technical Sales Representative

1965-68 Neville Chemical Company, Technical
Representative

1962-65 Co-op Student- Drexel Institute of Technology
GAF Corp.-Research Chemist
Atlas Chemical-QC Chemist
Drexel-Instructor-Freshman Chemistry

Academia:

Fairleigh Dickinson University
1982 to 2000
Adjunct Assistant Professor of Chemistry
Graduate School of Chemistry
"Skin Care Raw Materials"
"Hair Care Raw Materials"
"Chemistry of Cosmetic Raw Materials"

Center For Professional Advancement
"Cosmetic Preservation"
"Cosmetic Product Stability"
"Critical Components of Skin Products"
"Sunscreens" (Director)
"International Cosmetic Regulations"
"Labeling Over-the-Counter Drugs" (Director)

Society of Cosmetic Chemist, Continuing Education Program,
"Cosmetic Raw Materials"
"Preservatives for Cosmetics"

Memberships:

American Chemical Society
Institute of Food Technologists
Regulatory Affairs Professionals Society
Society of Cosmetic Scientists
Society of Cosmetic Chemists
Offices: New York Chapter Chair, 1979
National Treasurer, 1987-8
National President, 1991
Praesidium: International Federation of Societies of Cosmetic
Chemists, Honorary Auditor, 1992-5
Scientific Committee, 1995-8

Honors:

Society of Cosmetic Chemists, Merit Award, 1985
Society of Cosmetic Chemists, Fellow, 1987
Eminent Visiting Scholar, Virginia State University, 1987
Paper of the Year, 1988, Australian Society of Cosmetic
Chemists
IFSCC Sponsored Speaker, Brazil 1996, 2000

Miscellaneous: Columnist on International Cosmetic Regulations, *Cosmetics & Toiletries Magazine* 1995-present

Analyst, *Kosmet Data Base*, 1995-1998

Board of Directors, Hansotech, Inc. 1998

Board of Directors, ICMAD 1999-2003

Strategic Planning Advisory Board, Renaissance Pharmaceutical Company

Editorial Board *Journal of Cosmetic Science*, 1998

Editorial Board *Journal of Applied Cosmetology*, 1998

Advisory Board *Cosmetics & Toiletries* magazine
1997-present

Chairman, Preservatech Conference, 1998, Paris, France

Chairman, Preservatech Conference, 1999, Chicago, IL

Patent: 5,888,486 Antiperspirant Composition, 3/30/1999

Books:

Preservatives For Cosmetics, Allured Publishing, 1996

A Guide to European Cosmetic Regulations, ICMAD, 1998

Primary Ingredients, (With Anthony J. O'Lenick, Jr),
Hansotech Publication, 1998

FDA OTC Label Requirements Guidelines, Hirschhorn &
Young, 2000

Chapters:

Advanced Technology Conference 1996, Cosmetics &
Toiletries, Chapter on Cosmeceuticals: An American
Perspective

Transdermal and Topical Drug Delivery Systems, Co-
Author of Chapter: Topical Protective and Cosmetic
Products, Interpharm Press, 1997

Sun Products, Co-Author of Chapter: Encyclopedia of UV Absorbers for Sunscreen Products, Allured Publishing, 1998

Sunscreen Regulations: US, Europe, Australia and Japan, Co-Author of Chapter: Cosmetic Regulations in a Competitive Environment, Marcel Dekker, 2000

Antiperspirants and Deodorants, Author of Chapter: Regulations of Underarm Antiperspirants and Deodorants, Marcel Dekker, 1999

Botanicals in Cosmetics, Author of Chapter: The Regulation of Botanicals in Cosmetics, Marcel Dekker (expected 2002 ?)

The Chemistry and Manufacture of Cosmetics, Author of Chapter: Cosmetic Microbiology and Preservation, Allured Publishing Corp., 2000

Fundamentals of EU Regulatory Affairs, Author of Chapter: Cosmetics, RAPS, 2002

Legal Experience: Expert Witness: Revlon versus L'Oreal 1996-7. Paul Weiss, Rifkind, Wharton & Carrison Consultation, Expert Report, Depositions

Expert witness: Procter & Gamble versus Conopco, Inc. 1998. Howrey & Simon, Consultation, Expert Report

Consultation: Price, Heneveld, Cooper, DeWitt & Litton. Patents, Reports 1998-9

Consultation: R. Kunststadt, P.C. Patents 1999

Consultation: Olson & Hierl, Ltd. Patents 1998-02

Expert witness: DPT versus BBW 1999, Vorys, Sater, Seymour and Pease LLP 1999, Consultation

Expert Witness: Anita S. Nooe and Linwood Nooe v.
Unilever USA, Inc. 2000-1, Scruggs, Millette, Bozeman &
Dent
Expert Witness Report, Deposition, Consultation

Expert Witness: Alberta E. Richardson, et al. v. Carson
Products Company, Inc. et al. 2000-, Holland & Knight LLP,
Consultation, Deposition, Hearing

Expert Witness: Sandra L. Bronner, et al. v. Mercantile
Stores, Inc. 2000-1, ICE Miller, Consultation

Expert Witness: Johnson Marketing adv. Desert Dust
Cosmetics, 2000-2, Best Best & Krieger LLP, Consultation,
Depositions

Expert Witness: Taglieri v. Perrigo, et al. 2001-2, BHLaw,
Consultation, Court Testifying

Expert Witness: Sayles v. Johnson Products Company, Inc.
2001, Jackson & Kelley PLLC, Consultation

Expert Witness: Amy Nitz, et.al v. Vogue Hair Studio, Inc.
et.al, 2001-2 Barnes & Thornburg; Hoppe, Consultation,
Depositions

Expert Witness: Spa De Soleil Inc. V. Gary V Berger,
William R. Windette; R.T. Beers & Co. 2002- Ricks Rainey,
Consultation, Depositions

Regulatory Accomplishments:

Testified Before the FDA (at their request) on Sunscreen
Regulations, and Regulations of Over-The-Counter Drugs.

Authored the change in US regulations of OTC Drugs on the
acceptance of foreign data for US approvals.

Submitted and had approval from the European Union on
moving three prohibited ingredients in cosmetics, to being
allowed under restricted conditions. This was the first time in
the history of the EU cosmetic regulations that this was
achieved (2001-2).

David C. Steinberg

5/8/02

Publications

Synthetic Squalene for Cosmetics, *Drug & Cosmetic Industry* 129,3 September 81

Aminoefaderma: Aid to Skin Elasticity, *Cosmetic Technology* 3,11 November 81

Mucopolysaccharides for Cosmetics, *Cosmetic Technology* 4,2 February 82

Acanthogenesis in Oils for Skin, *Journal of the Society of Cosmetic Chemists* 32,2 March 82

Alternative Methods for the Formulation of Anhydrous Lipidic Systems for Topical Use, *Relata Technica* 31, 1982

Surfactants in Current Shampoos, *Relata Technica* 53, 1982

Germaben II- A Complete Preservative System in Clear Liquid Form
Cosmetic & Toiletries 97,11 November 1982

Cutaneous Effects of Various Lipoplastidines, *Drug & Cosmetic Industries* 132,2 February 1983

Protecting Shampoos with Two New Preservatives, *Cosmetic Technology* 5,2 February 1983

Cosmetic Preservatives, *Drug & Cosmetic Industries* 135,5 May 1984

A Review of Cosmetic Preservatives and Problems in Their Utilization, *Cosmetics Aerosols & Toiletries* 3,3 January 1989

Botanical Extracts and Preservation Issues, *Cosmetics & Toiletries* 106,2 February 1991

Preservatives, *Inform* 3,1 January 1992

Sodium Hydroxymethylglycinate-The Unique Preservative and Formulation Aid, *Proceedings the Australian Society of Cosmetic Chemists*, Feb. 1992

Cosmetic Preservation: Current International Trends, *Cosmetics & Toiletries* 107,9 September 1992

Maleated Soybean Oil and Its Multifunctional Properties, *Proceedings of In-Cosmetics*, Barcelona, 1994

The New Tentative Final USA Monograph on Sunscreens, *Proceedings of the 4th Joint Conference of the Australian and New Zealand SCC*, May 1994.

Preserving Foundations, Cosmetics & Toiletries 110,2 February 1995.

Liquid Parabens, The Next Generation of Preservation, Drug & Cosmetic Industry, 157, 4, October 1995.

Frequency of Use of Preservatives in the United States 1996, Proceedings of Preservatech 1996, pages 8-18.

Frequency of Use of Preservatives, Cosmetics & Toiletries 112,2 February 1997

"Natural" Preservatives, The Worldwide Directory for the Cosmetic Industry, 37-38, 1998

Waxes for the Third Millenium, Symposium on Cosmetics-The Next 50 Years, Manchester, UK, 1998

The Regulations of Personal Care Products in the USA and Global Harmonization, Conference Proceedings, International Cosmetic Expo, 1999

The Regulations of the Preservation of Cosmetics in the European Union, Proceedings of Preservatech 1999, pages 14-19

Animal vs. Vegetable: A Continuing Controversy, Skin, Inc. 11(2) April, 58-62, 1999

Grassi oli e cere, Cosmetic Technology, 2 (2), March 58-61, 1999

Caveat Emptor, Skin, Inc. 11(7) August, 46-51, 1999

Productos Elaborados con Drogas Filtradoras Solares Libres de Prescripción Médica: Monografía Final, Cosméticos Nuevos, 6 (1) February, 27-36, 2000

OTC Drug Facts Labeling, Conference Proceedings, International Cosmetic Expo, 2000

Sunscreen Drug Products for Over-The Counter Use: Final Monograph, Conference Proceedings, International Cosmetic Expo, 2000; Proceedings 34th Conference ASCC

A New Photostabilizer for Full Spectrum Sunscreens, Cosmetics & Toiletries 115 (6) 37-45, June 2000

Measuring Synergy, Cosmetics & Toiletries 115 (11) 59-62, November 2000

3

The Impact on Fragrances: The European Cosmetic Directive, *Global Cosmetic Industry*, 29-34, February 2002

A Modern Relationship, *Global Cosmetic Industry*, 30-34, March 2002

Frequency of Use of Preservatives 2001, *Cosmetics & Toiletries* 117 (4) 41-44, April 2002

Sunscreen Drug Products for Over-The Counter Use: Final Monograph, *Cosmetics Aerosols & Toiletries in Australia* 15 (1) 23-31 February 2002

European Cosmetic Regulatory Update, *Perfumer & Flavorist* 27 (3) 40-6, May/June 2002

Chapters in Books

Cosmeceuticals: An American Perspective, Advanced Technology Conference 1996 *Cosmetics & Toiletries*.

Topical Protective and Cosmetic Products, *Transdermal and Topical Delivery Systems*, Interpharm Press, 1997

Sunscreen Regulations: US, Europe, Australia and Japan, *Cosmetic Regulations in a Competitive Environment*, Marcel Dekker 2000

Encyclopedia of UV Absorbers for Sunscreen Products, *Sun Products*, Allured Publishing, 1998

Regulations of Underarm Antiperspirants and Deodorants, *Antiperspirants and Deodorants*, Marcel Dekker, 1999)

The Regulations of Botanicals in Cosmetics, *Botanicals in Cosmetics*, Marcel Dekker (Expected 2001)

Cosmetic Microbiology and Preservation, *The Chemistry and Manufacture of Cosmetics*, Author of Chapter: Allured Publishing Corp., 2000

Cosmetics, Fundamentals of EU Regulatory Affairs, Author of Chapter: RAPS, 2002

Books

Preservatives for Cosmetics, Allured Publishing, 1996

A Guide to European Cosmetic Regulations, ICMAD, 1998

Primary Ingredients, Hansotech, Inc. 1998

FDA OTC Label Requirements Guidelines, Hirschhorn & Young, 2000